**Caution: Federal (USA) law prohibits this device to sale by or on the order of a physician trained in gynecologic ultrasound**

# Package Insert

Package insert for USA use only

Notice d'utilisation pour utilisation exclusive aux États-Unis.
Packungsbeilage gilt nur in den USA.
Il foglietto illustrativo della confezione può essere usato solo negli USA.
Prospecto adjunto sólo para utilizarse en EUA.

## Device Description and Principle of Operation:

The **Her Option® Office Cryoablation Therapy System** is an office-based cryoablative treatment which uses a gas-cooled cryoprobe to ablate the endometrial lining of the uterus. Its operation is based on the Joule-Thomson principle in which pressurized gas is expanded through a small orifice to produce cooling. The coolant or gas used in the system is a proprietary blend of commonly used coolants, which are non-toxic, non-corrosive, non-flammable and non-CFC.

The system is intended to destroy tissue during ablation procedures by the application of extreme cold at the distal tip of the Cryoprobe. A -20°C temperature is lethal to tissue. The ice front advances through the uterine tissue, creating a CryoZone, rather than expanding within the endometrial cavity.

The **Her Option® Office Cryoablation Therapy System** includes a Console, a Cryoprobe and a Disposable Probe. The Cryoprobe with Disposable Probe attached is referred to as the Probe. A compressor housed in the Console is fully charged with coolant and is semi-hermetically sealed prior to shipping to ensure zero leakage. Activation of the System freeze cycle causes gas to exit the compressor and flow to the Probe where it expands to a low pressure across a small diameter orifice at the tip of the Probe. As a result, a rapid temperature drop occurs. This temperature drop is transferred to the tissue-contacting tip of the Disposable Probe, causing freezing. Gas then returns to the compressor and is recirculated. Deactivation of the freeze cycle stops gas flow to the Probe, ending cooling. The sterile **Her Option® Office Cryoablation Therapy** Disposable Probe is sold separately.

## Indications:

The **Her Option® Office Cryoablation Therapy System** is a closed-cycle cryoablative device intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia or excessive bleeding due to benign causes for whom childbearing is complete.

## Contraindications:

The device is contraindicated for use in:

- A patient who is pregnant or who desires to become pregnant in the future. *(Pregnancies following ablation can be dangerous for both mother and fetus).*
- A patient with a known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium such as unresolved adenomatous hyperplasia.
- A patient with an active genital or urinary tract infection at the time of the procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis).
- A patient with active pelvic inflammatory disease (PID).
- A patient with an intrauterine device (IUD) currently in place.
- A patient with any anatomic or pathologic condition e.g. chronic immunosuppressive therapy, in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy.

## Warnings:

**Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.**

**Office Based**

As is the case with office based procedures such as endometrial biopsy, loop electrosurgical excision procedure [LEEP], hysteroscopy and endometrial ablation, physicians that perform HerOption Office Cryoablation Therapy should follow these general recommendations:

- Vasovagal effects can occur with any manipulation of the cervix. Office personnel should be trained in airway management, with advanced cardiac life support.
- Prepare an emergency kit with appropriate pharmacological agents to assist in managing emergency situations; be prepared to check blood pressure and provide hemostasis for cervical lacerations.
    - Know your local anesthetic's maximum dose. To avoid the risk of overdose draw out the maximum dosage. Overdose symptoms include: dizziness, lightheadedness, tinnitus, depression, and systole. In case of severe reaction be prepared to administer appropriate pharmacological agents.

**General**

- Although endometrial ablation with the **Her Option® Office Cryoablation Therapy System** significantly decreases the likelihood of pregnancy, it is not a sterilization procedure. The patient should be advised of appropriate birth control methods.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia, or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation are at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post procedure.

**Technical**

- Endometrial ablation procedures using the **Her Option® Office Cryoablation Therapy System** should be performed only by medical professionals who have experience in performing procedures within the uterine cavity, such as IUD insertion or dilation and curettage (D&C) and who have adequate training and familiarity with use of the Her Option™ System.
- The sterile **Her Option® Office** Disposable Probe is for single use only. Do not attempt to re-sterilize or reuse.
- Use caution not to perforate the uterine wall when sounding the uterus or inserting the Cryoprobe. If a perforation is present, the procedure should be terminated immediately.
- There is the potential for thermal injury to adjacent organs if the CryoZone extends beyond the serosal surface of the uterus; therefore, it is necessary to visualize and monitor the growth of the CryoZone with ultrasound. The freeze cycle should be stopped if the leading edge of the CryoZone approaches within 2mm the serosal surface.

## Precautions:

- Endometrial ablation procedures using the **Her Option® Office Cryoablation Therapy System** should be performed only by physicians trained in gynecologic ultrasound.
- It has been reported in the literature that patients with a severely anteverted, retroflexed or laterally displaced uterus are at greater risk of uterine wall perforation during any intrauterine manipulation.
- A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of severely anteverted, retroflexed or laterally displaced uterus. Use caution to ensure that the device is properly positioned in the uterine cavity.
- The **Her Option® Office Cryoablation Therapy System** is a sealed system. Tampering with the Console or Cryoprobe may result in loss of gas and loss of effectiveness.
- Clean and disinfect the stainless steel Cryoprobe according to instructions under "Sterilization and Cleaning" in the User's Manual. Do not autoclave. Do not immerse cryoprobe in liquids.
- Do not use the Disposable Probe if there is any evidence of tampering or damage to the sterile package.
- It is very important that the PreCool cycle be conducted using the Disposable Probe that will be used for the treatment. Test probes should **NOT** be used for PreCool cycle.

- To ensure that the system is operating properly, a PreCool cycle or a test freeze cycle should be conducted in air with every new disposable probe prior to placing probe in patient. If the disposable probe is switched during a procedure for any reason, a test freeze cycle in air should be initiated by pressing the minus (-) button immediately. Verify that the temperature reading on the console reaches -50º C.
- Always monitor the temperature on the console display and verify that it is reading the temperature as expected (i.e., temperature is decreasing during cooling cycles and increasing during heating cycles).
- Spark generation is possible: DO NOT use the system in an oxygen rich environment.
- Do not bend the Cryoprobe or the Disposable Probe**.**
- The Flexline is delicate and consists of four separate tubes each carrying fluids. Avoid sharp bending of the Flexline or pulling on the Flexline as a means of moving the **Her Option® Office Cryoablation Therapy** Console.
- If the power is interrupted during one of the freeze cycles or the display temperature fails to achieve 20° C use room temperature normal saline to accelerate the heating process and allow removal of the Probe.
- Do not attempt to disassemble the **Her Option® Office Cryoablation Therapy** Console, Cryoprobe or sterile Disposable Probe.
- DO NOT allow the ventilation holes on the Console to become obstructed, damage may occur.
- The Probe tip may become adherent to the tissue during freezing. Allow adequate time during the heat cycle for tissue to warm before attempting to remove the Probe (approximately 2 minutes, or when the temperature achieves 20° C). Do not attempt to remove Probe from tissue if there is significant resistance. If an error condition exists, use room temperature saline, rather than the heat cycle to loosen the probe from the tissue.
- Patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have progestin included in their medication regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of **Her Option®Office Cryoablation Therapy System** for ablation of the endometrial lining of the uterus has not been fully evaluated in patients:
  - with a uterus greater than 300cc in volume or a uterine sound greater than 10 cm,
  - with a uterine sound less than 4 cm
  - who have undergone a previous endometrial ablation procedure,
  - with intramural myomas >2 cm in diameter, intrauterine polyps, or pedunculated fibroids,
  - with a septate uterus, or,
  - who are post-menopausal.

**Adverse Events:**

The **Her Option®Office Cryoablation Therapy System** was evaluated in a randomized, prospective, multi-center clinical study, comparing the Her Option™ Cryoablation Therapy to a control arm of rollerball endometrial ablation (REA). There were no reported incidents of serious device-related adverse events in the cryoablation group. Tables 1a - 1c summarize the adverse events for the 272 patients treated in this study:

**Table 1a - Adverse Events During Procedure and within 24 hours Post-Procedure**

| Adverse Event | Cryoablation n=186 | REA n=86 |
|---|---|---|
| Uterine cramping | 15 (8%) | 4 (5%) |
| Other abdominal or pelvic pain/cramping | 27 (15%) | 10 (12%) |
| Nausea and vomiting | 4 (2%) | 4 (5%) |
| Hot flashes | 2 (1%) | 0 (0%) |
| Hyponatremia/Fluid Overload | 0 (0%) | 3 (3%) |
| Perforation* | 1 (.5%) | 1 (1%) |
| Cervical/vaginal laceration | 0 (0%) | 1 (1%) |

***Cryo perforation occurred during sounding prior to treatment. REA perforation occurred during treatment.***

**Table 1b - Adverse Events at 2 week Post-Procedure**

| Adverse Event | Cryoablation n=186 | REA n=86 |
|---|---|---|
| Uterine cramping | 5 (3%) | 0 (0%) |
| Other abdominal or pelvic pain/cramping | 7 (4%) | 8 (9%) |
| Urinary tract infection (UTI) | 5 (3%) | 3 (3%) |
| Hot flashes | 6 (3%) | 3 (3%) |
| Vaginal infection | 2 (1%) | 1 (1%) |
| Nausea/vomiting | 2 (1%) | 2 (2%) |

**Table 1c -- Adverse Events at 3, 6, and 12 months Post-Procedure***

| Adverse Event | Cryoablation Group n=186 | REA Group n=86 |
|---|---|---|
| Uterine cramping | 7 (4%) | 5 (6%) |
| Other abdominal or pelvic pain/cramping | 26 (14%) | 16 (19%) |
| Vaginal infection | 7 (4%) | 1 (1%) |
| Hot flashes | 3 (2%) | 7 (8%) |
| Urinary tract infection | 2 (1%) | 3 (3%) |
| Nausea/vomiting | 1 (.5%) | 1 (1%) |

*Below is a more detailed description of the Adverse Events reported above:

- **Pelvic Pain/Cramping** – Peri-operative cramping typically lasted a few hours and rarely continued beyond the first day following ablation. Some of the mild cramping was reported as resolved without medication. The use of non-steroidal anti-inflammatory drugs (NSAID's) was reported to typically manage the cramping and pain.
- **Nausea and Vomiting** – Nausea and vomiting was managed with medication.
- **Bladder Infection/Vaginal Infection** – The infections were managed with oral antibiotics.
- **Other Events** – Other Adverse Events reported which occurred in no greater than 1% of the patients treated with **Her Option®** include: severe bleeding (more than two weeks following the procedure), difficulty recovering from anesthesia and pregnancy (1 patient).

**Other Adverse Events:**

As with all endometrial ablation procedures, serious injury or death can occur. The following adverse events could occur or have been reported in association with the use of the **Her Option® Cryoablation Therapy System**:

- Endometritis
- Difficulty with defecation or micturation
- Hematometra
- Thermal injury to adjacent tissue
- Hemorrhage
- Post ablation tubal sterilization syndrome
- Perforation of Uterus
- Complications with pregnancy (Note: Pregnancy following any endometrial ablation procedure is dangerous to both the mother and the fetus.)
- Uterine necrosis
- Infection or sepsis
- Complications leading to serious injury or death

**Clinical Study:**

**Purpose:** The use of cryoablation in the treatment of menorrhagia from benign causes in pre-menopausal women was compared to REA to evaluate safety and effectiveness.

**Study Endpoints:** The primary effectiveness measure was a validated menstrual diary scoring system developed by Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart (Br J Obstet Gynaecol 1990;97:734-9). Patient success was defined as a reduction in menstrual flow at 1 year to a diary score of $\leq$75. Study success was defined as a statistical difference of less than 20% in patient success rates between Cryoablation and REA. Secondary endpoints included responses from a quality-of-life questionnaire. Safety

evaluation was based on the adverse events reported during the study, including device-related complications. The type of anesthesia required to complete the procedure was also recorded.

**Methods**: A randomized (2:1), prospective study was conducted at 10 clinical sites which included 275 patients diagnosed with menorrhagia. Study subjects were required to meet the following key inclusion/exclusion criteria

Inclusion criteria:

- Premenopausal female, between 30 and 50 years of age, in good general health
- Documented history of excessive uterine bleeding and a completed pictorial blood assessment chart (PBAC) of >150 for at least one menstrual cycle
- Previously failed or refused traditional medical therapy, D&C and Depo-Provera
- Uterine sound measurement $\leq$ 10 cm
- Uterine volumetric measurement $\leq$ 300 cc.
- Patient does not desire to maintain fertility

Exclusion criteria:

- Clotting defects or bleeding disorders
- Poor general health
- Patient below age 30 or above age 50
- Active pelvic inflammatory disease
- Abnormal pap smear within the previous year, unless appropriately evaluated
- History of gynecologic malignancy within the past 5 years
- Intramural myomas greater than 2 cm diameter
- Intrauterine polyps
- Pedunculated fibroids
- Septate uterus
- Previous endometrial ablation procedure or other uterine surgery in which thinning of the uterine musculature occurs
- Malignant pathology or hyperplasia within the previous six months, as documented by endometrial biopsy
- Pregnancy
- Women who desire to maintain fertility

Menstrual diary scores were collected pre-treatment and at 3, 6 and 12 months post-treatment. Patients were given Lupron (3.75mg) 28 days prior to the cryoablation therapy.

**Patient Population:**

A total of 279 patients were enrolled in this study in a 2:1 ratio of Cryoablation to Rollerball respectively. Baseline characteristics between Cryoablation and REA patients were compared and found to be statistically equivalent with regard to age, body mass index, gravidity, parity, full-term deliveries, previous Cesarean section, previous D&C, previous tubal ligation, presence of fibroids or myomas, cavity sounding length, severe menstrual pain and cramping, severe PMS symptoms, medical therapy for menorrhagia, hematocrit and FSH. One variable, pretreatment PBAC diary scores demonstrated moderate statistical significance ($p<0.05$). Median pretreatment PBAC scores were higher in the group treated with cryoablation.

## Subject Accountability

| | Cryoablation | REA | TOTAL |
|---|---|---|---|
| Intent to Treat Population | 193 | 86 | 279 |
| Subject Withdrawals | -4 | 0 | -4 |
| Complications/Incomplete Treatment | -6 | -1 | -7 |
| Complete Treatments | 183 | 85 | 268 |
| Subjects not available at 12 Month Follow-up | | | |
| Lost to follow-up | -14 | -8 | -22 |
| Hysterectomy | -6 | -3 | --9 |
| Repeat Ablation | -5 | -1 | -6 |
| Population with 12-Month Data Available | 158 | 73 | 231 |
| Subjects not available at 24 Month Follow-up | | | |
| Lost to follow-up | -60 | -29 | -89 |
| Hysterectomy | -8 | -8 | -16 |

| | | | |
|---|---|---|---|
| Population with 24-Month Data Available | 90 | 36 | 126 |
| Subjects not available at 36 Month Follow-up<br>Lost to follow-up<br>Hysterectomy | <br>0<br>-2 | <br>-0<br>-1 | <br>-0<br>-3 |
| Subjects Lost to Follow-up at 24 months, returned at 36 Months | +15 | +3 | +18 |
| Population with 36-Month Data Available | 103 | 38 | 141 |

**Results:**

***Primary Effectiveness Endpoint***

Patient success was based on a reduction in excessive uterine bleeding to normal levels or better. A success at 12-months post procedure is defined as a reduction in diary scores from $\geq$ 150 pre-treatment to $\leq$ 75. Amenorrhea is defined as a score of 0. Success at 24 and 36 months is defined as Amenorrhea (no bleeding), Hypomenorrhea (light bleeding), or Eumenorrhea (normal menstrual bleeding) as reported by subject via questionnaire. Results at 12, 24 and 36-months post-treatment are presented below for the Intent to Treat (ITT) Population.

**Table 2: Effectiveness: Bleeding Rates for the Intent to Treat Population†**

| **Intent to Treat Population: N = 279** | **Cryoablation n = 193** | | | **REA n = 86** | | |
|---|---|---|---|---|---|---|
| **Months post treatment** | **12[a]** | **24[b]** | **36[b]** | **12[a]** | **24[b]** | **36[b]** |
| Number of successful subjects | 130 | 60 | 76 | 63 | 29 | 29 |
| Study success rate | 67% | 31% | 39% | 73% | 34% | 34% |
| Number of subjects with Amenorrhea | 43 | 15 | 22 | 40 | 17 | 17 |
| Amenorrhea rate | 22% | 8% | 11% | 47% | 20% | 20% |

† Intent to Treatment (ITT) population represents all subjects enrolled in the study including those considered as failures because they were not available for follow-up, did not receive treatment, and/or received partial treatment. Therefore, the ITT group represents a worse case scenario for effectiveness.
See Subject Accountability section for complete accounting of all subjects enrolled in the study.

[a] Based on diary score.

[b] Based on questionnaire response.

***Secondary Effectiveness Endpoint***

Quality of Life (QOL) information was obtained by comparing QOL scores obtained via questionnaire at pre-treatment and at 12, 24, and 36 months post-treatment. These scores were compared and the results are presented below.

**Effectiveness: Quality of Life**

Quality of Life (QOL) data was obtained at one year post-operatively using the SF-36 Health Survey as well as a version of the validated Dartmouth COOP assessment tool. Because there are no QOL questions pertaining to menorrhagia, approval from the Dartmouth Committee was granted to use the same style of questions and format them according to the study design. Parameters included SF-36 PMS symptoms and menstrual pain indices. A telephone survey was also conducted at 2 and 3-years post-operatively. Table 3 summarizes QOL responses to the survey.

**Table 3: Quality of Life (QoL) Scores Out to 3-Years Post-Treatment**

| | CRYO | REA |
|---|---|---|
| Effect on QoL* (1=Not at all, 5-=Extremely) | | |
| Pre-operatively (CRYO=180, REA=82) | 3.4 $\pm$ 1.0 | 3.5 $\pm$ 0.9 |
| 1 Year (CRYO=157, REA=73) | 1.3 $\pm$ 0.7 | 1.3 $\pm$ 0.9 |
| 2 Years (CRYO=72, REA=25) | 1.3 $\pm$ 0.78 | 1.4 $\pm$ 0.91 |
| 3 Years (CRYO=75, REA=22) | 1.3 $\pm$ 0.8 | 1.5 $\pm$ 1.1 |

| | | |
|---|---|---|
| Percentage of subjects reported time lost from work/other activities* | | |
| Pre-operatively (CRYO=180, REA=82) | 74% | 71% |
| 1 Year (CRYO=157, REA=73) | 6% | 7% |
| 2 Years (CRYO=74, REA=25) | 8% | 8% |
| 3 Years (CRYO=76, REA=22) | 8% | 9% |
| Percentage of subjects very/extremely satisfied** | | |
| 1 Year (CRYO=157, REA=73) | 86% | 88% |
| 2 Years (CRYO=90, REA=36) | 90% | 86% |
| 3 Years (CRYO=103, REA=38) | 89% | 82% |
| Percentage of subjects who would recommend therapy to a friend** | | |
| 1 Year (CRYO=157, REA=73) | 96% | 94% |
| 2 Years (CRYO=89, REA=36) | 97% | 94% |
| 3 Years (CRYO=102, REA=37) | 97% | 97% |

* Responses include only subjects experiencing menstruation or symptoms. Those not menstruating or experiencing symptoms did not complete this section of the questionnaire.
**Responses were not recorded for all subjects.

**Safety Endpoint**
Adverse event information is described in the "Adverse Events" section of this manual.

**Anesthesia and Dilation**
Anesthesia was delivered at the discretion of the investigator and attending anesthesiologist. General anesthesia was administered to 92% (79/86) of the REA patients and 46% (85/186) of the cryoablation patients. Of the cryoablation group, 39% (72/186) of the patients received a paracervical block with conscious sedation as compared to only 1% (1/86) of the REA group.

There are data specific to the degree of dilation available on 164 cryoablation patients and 76 REA patients. Of these patients, twenty-one (11%) of the cryoablation patients did not receive any dilation, whereas all (100%) REA patients received some degree of dilation. This difference is statistically significant with a p value of 0.0003.

**Clinical Study Observations**

**Hysterectomy**

There were a total of 28 patients (#16 Cryoablation; 12 REA) who had hysterectomies within 3 years following endometrial ablation.

**Table 4: Summary of Reasons for Hysterectomy within 3 years**

| Reason for Hysterectomy | Cryoablation (n=193) | REA (n=86) |
|---|---|---|
| Menorraghia/Abnormal Uterine Bleeding | 10 | 6 |
| Unreported/Unknown | 4 | 1 |
| Pain/Fibroids | 2 | 2 |
| Ovarian Cyst | 0 | 1 |
| Ovarian Cancer | 0 | 1 |
| Severe PMS | 0 | 1 |
| Total | 16 | 12 |

Ten Hysterectomies were in patients <40 years (6 Cryoablation; 4 REA); 18 hysterectomies were in patients ≥40 years (10 Cryoablation; 8 REA) based on age at the time of the cryoablation therapy

**Patient Selection:**

Menorrhagia can be caused by a variety of underlying problems including, but not limited to, endometrial cancer, hormone imbalance, anovulation, drugs, myomas and polyps. Patients should be thoroughly evaluated to determine the cause of the menorrhagia prior to any treatment being initiated.

**Patient Selection for Office Based Procedures:**

Patients with the following conditions may not be appropriate candidates for office based procedures:

- Patients who have uncontrolled anxiety, pain, or moderate systemic diseases (such as hypertension, arrhythmias, arteriosclerotic vascular disease, severe obstructive lung disease)
- Patients who have a difficult anatomy which impedes ultrasound visualization.

**Patient Information:**

Patients should be counseled regarding the risks, benefits and alternatives prior to the performance of this procedure. This counseling should include the need for post-procedure contraception where indicated. This procedure is not a sterilization procedure and subsequent pregnancies may be dangerous for the mother and fetus.

Vaginal discharge is possible following the procedure. This may last from a few days to a few weeks. Any unusual or foul smelling draining should be reported to the physician immediately.

**Pre-Op Work Up:**

The Pre-op work up should include: History and complete physical examination, including pelvic exam; Negative PAP smear and endometrial biopsy to rule out cervical or endometrial malignancy and pre-malignant changes to the uterus; Sonography, hysteroscopy, hystero-salpingography or any other indicated diagnostic test or procedure that might uncover a possible cause for menorrhagia within six months of performing the Her Option® procedure.

**Pre-Treatment Preparation of Patient:**

It is recommended that the lining of the uterine cavity be thinned prior to **Her Option® Office Cryoablation Therapy**. Thinning can be accomplished by administering a GnRH agonist 21 – 28 days prior to the procedure or performing suction curretage immediately prior to the cryoablation procedure.

A non-steroidal anti-inflammatory drug (NSAID) may be given to the patient one hour prior to the treatment and continued post-operatively as needed.

**Clinical Use Checklist:**

Prior to using **Her Option® Office Cryoablation Therapy** for the first time, physicians should be trained and familiar with the following procedures and techniques:

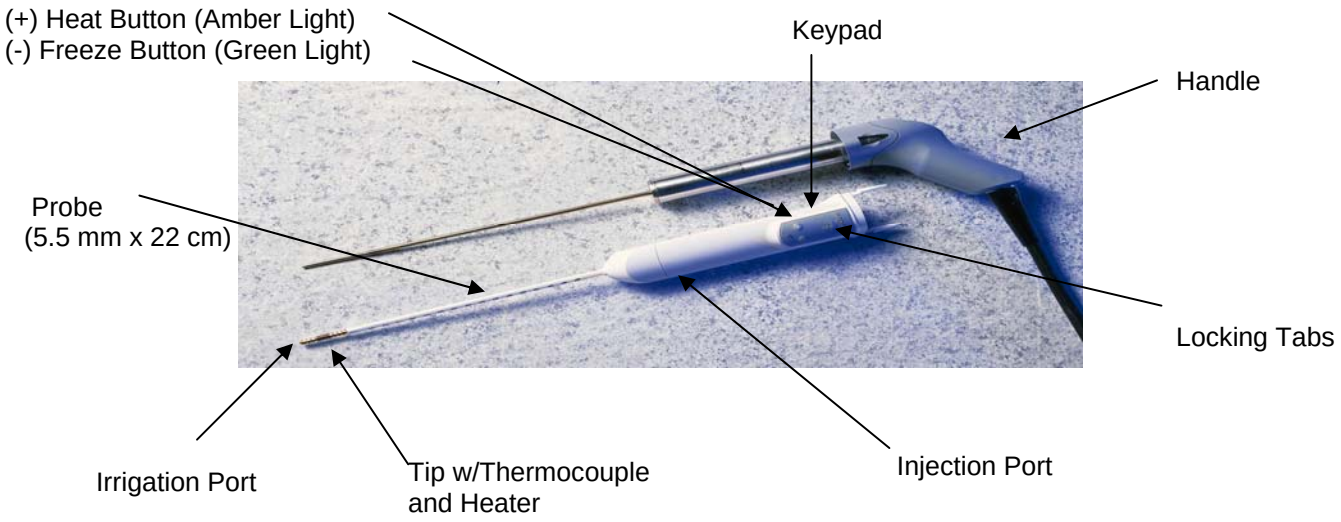
- intrauterine gynecological procedures;
- recognizing the tip of the probe in the uterus and the CryoZone as it advances toward the serosa;
- placing the tip of the probe in the uterine cornu;
- confirming (via ultrasound) maintenance of the proper placement of the probe tip, and
- cryoablation of the cervix

The physician, as well as adjunctive personnel, should review and be familiar with the **Her Option® Office Cryoablation Therapy System** training material (User's Manual, training video, Clinical Use protocol).

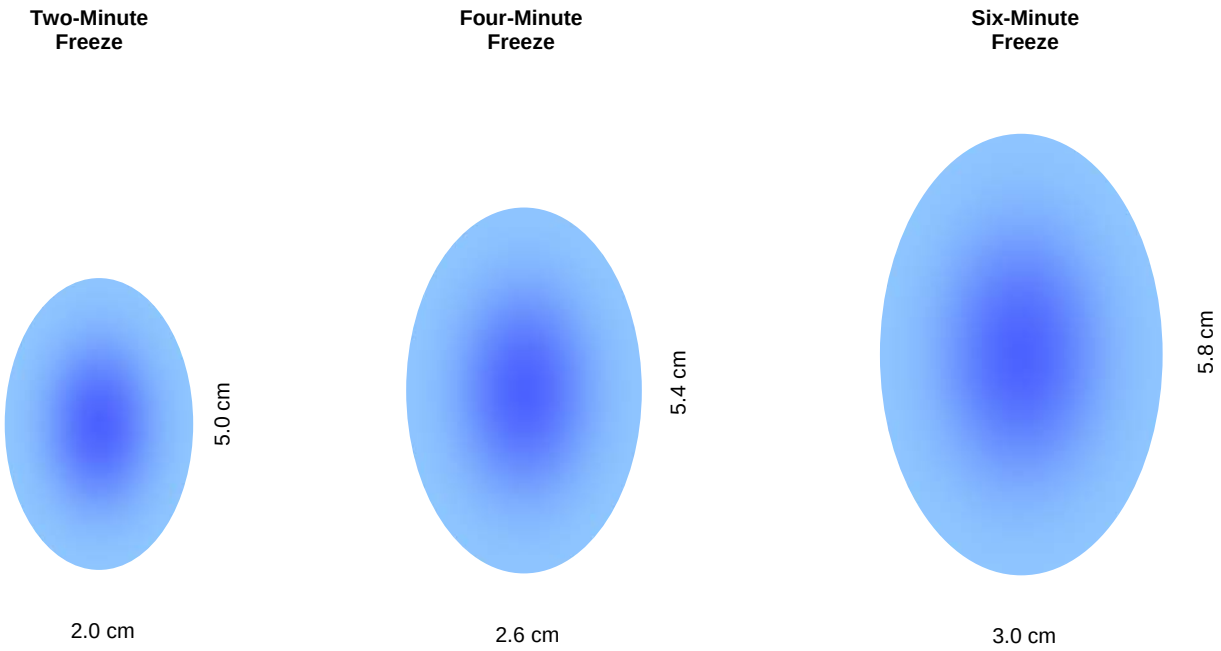
**Power Source:**

| | Specification |
|---|---|
| Voltages | 100/120/220/240 $V_{RMS}$ |
| Frequency | 50/60 Hz |
| Rating | 1200 VA |

**PROBE (CRYOPROBE WITH A DISPOSABLE PROBE)**




## Average CryoZone Dimensions*




*The CryoZone dimensions illustrated above were obtained during in-vitro testing in media that simulates tissue. Please note that the illustrations above represent the growth of the CryoZone over a period of time. Ultrasound provides visualization of the CryoZone and the proximity of the leading edge to the serosal surface of the uterus. (ETR 04060)

## Article Reference:

Levy, Barbara A., Isaacson, Keith. *Office-based treatment of abnormal uterine bleeding;* OBG Management. September 2003.

**Physician Preparation:**

Physician preparation for procedure is dictated by the site of service (i.e., office setting, ASC, operating room, etc.) and local practice standard.

**Site Preparation:**

1. Patient is placed in dorsal lithotomy position.
2. Physician prepares perineum, vagina and cervix with antiseptic solution per local practice.
3. Physician uses sterile drape exposing perineum only.
4. Physician conducts pelvic examination to determine size, shape and position of cervix and uterus.
5. Physician sounds cervix and uterus.
6. Physician employs speculum and/or retractors, and sufficient illumination so as to provide adequate visualization of the cervix.

**Directions For Use:**

***The following directions provide some of the salient points for the use of Her Option® Office Cryoablation Therapy System. Please read the User's Manual before operating the system.***

The use of the Her Option® Office Cryoablation Therapy System requires two people, a non-sterile *Assistant* and a sterile-gloved *Physician.* The Console display provides information that will help guide you during the procedure – pay attention to the screen display.

The sterile Disposable Probe should always be handled using sterile technique. To attach the Disposable Probe to the Cryoprobe, use a slow steady motion and gently push the Disposable Probe until the locking tabs are fully engaged into the Cryoprobe handle.

A PreCool Cycle must be performed immediately prior to use. The PreCool Cycle will last approximately 2-5 minutes and the heating portion ends when the heater automatically warms up to 37°C. Begin the first freeze within 60 minutes of the PreCool Cycle, otherwise, the PreCool Cycle may have to be repeated. The user will be prompted if a Precool is necessary. The Precool Cycle should be performed with the Probe outside the patient's uterus. **Caution: It is very important that the PreCool cycle be conducted with the Disposable Probe that will be used for the treatment. Test probes should not be used for PreCool cycle.**

You may need to dilate the cervix to 6mm. For optimal image when using ultrasound guidance in positioning the Probe, the bladder should be full to ensure adequate ultrasound imaging. 5-10cc of saline injected into the uterus eliminates air pockets and will ensure good thermal contact between the Probe and the tissue.

The first freeze cycle should be terminated by depressing the Heat (+) button after 4 minutes, or earlier if ultrasound imaging indicates that the CryoZone leading edge approaches 2mm of the serosal surface of the uterus. At the completion of the heat cycle, inject 5-10cc of saline and reposition towards the opposite lateral cornu. Verify correct placement with ultrasound. If probe resistance is encountered during the second placement, inject warm saline to expedite the thawing process of initial CryoZone. Confirm appropriate placement by injecting saline in the uterine cavity and identifying the flow of saline using ultrasound guidance. In addition, ultrasound visualization can be used to verify that the placement of the probe is out of the first CryoZone by visualizing the tip while sliding the probe in and out for approximately 1 cm.

The second freeze should last for only 6 minutes, or less if the CryoZone leading edge approaches 2mm of the serosal surface.

Note: The Probe should only be withdrawn from the CryoZone when the registered tip temperature is above 20°C.

**For Immediate Technical Support, Call: U.S. 800-328-3881**
**Outside U.S. 01-952-930-6000**

**STERILIZATION METHOD GAMMA**

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